OCT 18 2011

A-SPINE

## 510(k) Summary

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| **Date:** | 28 June 2011 |
| **Sponsor:** | A-SPINE ASIA CO., LTD.<br>11F., No. 1, Aly. 30, Ln. 358, Ruiguang Rd., Neihu District, Taipei, Taiwan<br>Phone: +886 (2)2627-2977<br>Fax: +886 (2)6606-5955 |
| **Contact Person:** | Frank Hsu<br>A-SPINE ASIA CO., LTD.<br>11F., No. 1, Aly. 30, Ln. 358, Ruiguang Rd., Neihu District, Taipei, Taiwan<br>frank@aspine.com.tw<br>Phone: +886 (2)2627-2977<br>Fax: +886 (2)6606-5955 |
| **Proposed Trade Name:** | SmartLoc™ spinal fixation system |
| **Device Classification** | Class II |
| **Classification Name:** | Pedicle screw spinal system & Spinal interlaminal fixation orthosis |
| **Regulation:** | 888.3070 & 888.3050 |
| **Device Product Code:** | MNI/MNH & KWP |
| **Device Description:** | The SmartLoc™ consists of rods, monoaxial and polyaxial pedicle screws, hooks and transverse connectors with locking set screws. The components are available in various sizes to accommodate differing patient anatomy. Rods are available in one diameter and a variety of lengths. Monoaxial and polyaxial screws are available in a variety of diameter-length combinations. Hooks are offered in a variety shapes and sizes. |
| **Intended Use:** | The SmartLoc™ is a spinal fixation system intended to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments as an adjunct to fusion. When used as posterior, pedicle screw fixation, the system is intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients. In addition, when used as a pedicle screw fixation system in the noncervical posterior spine (T1 to S2), the system is intended for the treatment of the following acute and chronic instabilities or |

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| | deformities: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion in skeletally mature patients. When used as a posterior, non-cervical, hook and/or sacral/iliac fixation system (i.e., non-pedicle screw), the SmartLoc™ is intended for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (as conformed by patient history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion. |
| **Materials:** | The SmartLoc™ components are manufactured from titanium alloy (Ti-6Al-4V) as described by ISO 5832-3 / ASTM F136. |
| **Predicate Devices:** | CD HORIZON® (K031655/K041460)<br>Moss Miami (K992168/K022623)<br>Synergy VLS (K950099/K974749)<br>Optima™ (K024096/K031585/K051971)<br>flamenco (K102853) |
| **Technological Characteristics:** | The SmartLoc™ possesses the same technological characteristics as the predicate devices. These include<br>● basic design (rod-based fixation system having monoaxial and polyaxial pedicle screws and various hook shapes and sizes),<br>● material (titanium alloy),<br>● sizes (rod and screw sizes are encompassed by those offered by the predicate systems) and<br>● intended use (as described above).<br>The fundamental scientific technology of the SmartLoc™ is the same as previously cleared devices. |
| **Performance Data:** | Static compression bending and torsion, and dynamic compression bending of the worst case SmartLoc™ construct was performed according to ASTM F1717. The mechanical test results demonstrated that SmartLoc™ performs as well as or better than the predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 18 2011

A-Spine Asia, Co., LTD.
% Mr. Frank Hsu
11F., No. 1, Aly. 30, Ln. 358
Ruiguang Rd., Neihu District, Taipei
Taiwan

Re: K111883
Trade/Device Name: SmartLoc™ spinal fixation system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal ssytem
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: September 14, 2011
Received: September 15, 2011

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K111883

Device Name: **SmartLoc™ spinal fixation system**

Indications for Use:

The SmartLoc™ is a spinal fixation system intended to provide immobilization and stabilization of thoracic, lumbar, and sacral spinal segments as an adjunct to fusion.

When used as posterior, pedicle screw fixation, the system is intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients. In addition, when used as a pedicle screw fixation system in the non-cervical posterior spine (T1 to S2), the system is intended for the treatment of the following acute and chronic instabilities or deformities: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion in skeletally mature patients.

When used as a posterior, non-cervical, hook and/or sacral/iliac fixation system (i.e., nonpedicle screw), the SmartLoc™ is intended for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (as conformed by patient history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal stenosis, spinal tumor, pseudarthrosis and failed previous fusion.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices